# General

## Guideline Title

Management of primary cutaneous squamous cell carcinoma. A national clinical guideline.

## Bibliographic Source(s)

Scottish Intercollegiate Guidelines Network (SIGN). Management of primary cutaneous squamous cell carcinoma. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2014 Jun. 44 p. (SIGN publication; no. 140). [86 references]

## Guideline Status

This is the current release of the guideline.

Any amendments to the guideline in the interim period will be noted on the Scottish Intercollegiate Guidelines Network (SIGN) Web site .

This guideline meets NGC's 2013 (revised) inclusion criteria.

# Recommendations

## Major Recommendations

*Note from the Scottish Intercollegiate Guidelines Network (SIGN) and National Guideline Clearinghouse (NGC): In addition to these evidence-based recommendations, the Guideline Development Group also identifies points of best clinical practice in the full-text guideline document.*

The grades of recommendations (strong, conditional) and levels of evidence (1++, 1+, 1-, 2++, 2+, 2-, 3, 4) are defined at the end of the "Major Recommendations" field.

Identifying High-Risk Tumours

Clinical Features

*Immune Status*

Immunosuppression should be considered a high-risk clinical feature in patients with primary squamous cell (SCC) carcinoma.

*Tumour Site*

The ear should be considered the highest risk tumour site in patients with primary SCC.

*Maximum Clinical Diameter*

Clinically determined horizontal tumour diameter of >20 mm should be considered a high-risk feature in patients with primary SCC.

Pathological Features

*Tumour Depth/Level of Invasion*

Tumour depth >4 mm should be considered a high-risk feature in patients with primary SCC with depth >6 mm indicating a very high-risk tumour.

Tumour extension beyond the dermis into or through subcutaneous fat should be considered a high-risk feature in patients with primary SCC.

*Maximum Tumour Diameter*

Tumour horizontal diameter of >20 mm should be considered a high-risk feature in patients with primary SCC.

*Perineural Invasion*

Perineural invasion should be considered a high-risk feature in patients with primary SSC.

*Tumour Subtype*

Desmoplastic subtype should be considered a high-risk feature in patients with primary SSC.

*Differentiation*

Poorly-differentiated tumour status should be considered a high-risk feature in patients with primary SCC.

Referral to the Multidisciplinary Team (MDT)

Where any of the following high-risk features are present, patients with primary SCC should be discussed at a skin cancer MDT meeting:

- SCC arising on the ear
- Tumour diameter >20 mm
- Tumour thickness >4 mm
- Tumour extension beyond dermis into or through subcutaneous fat
- Perineural invasion
- Poorly differentiated
- Desmoplastic subtype
- Immunosuppression

Therapeutic Interventions

Surgical Techniques

*Standard Surgical Excision*

For high-risk tumours a clinical peripheral margin of 6 mm or greater is indicated, where surgically achievable and clinically appropriate.

For low-risk tumours a clinical peripheral margin of 4 mm or greater is indicated where surgically achievable and clinically appropriate.

*Mohs Micrographic Surgery*

Mohs micrographic surgery should be considered at the MDT, for selected patients with high-risk tumours where tissue preservation or margin control is challenging, and on an individual case basis for patients with any tumour at a critical anatomical site.

Destructive Techniques

*Curettage and Cautery*

Curettage and cautery can be considered for patients with low-risk SCCs, if healthcare professionals have had appropriate training with a blunt curette.

*Photodynamic Therapy*

Photodynamic therapy should not be used for treatment of primary SSC.

Radiotherapy

*Primary Radiotherapy*

Primary radiotherapy should be considered for individual patients where surgical excision would be extremely challenging or difficult to perform or would be likely to result in an unacceptable functional or aesthetic outcome.

*Adjuvant Radiotherapy*

Adjuvant radiotherapy should be considered for patients with a high risk of local recurrence or with close or involved margins where further surgery may be associated with increased risk of complications including functional or aesthetic morbidity.

Systemic Retinoids

Selected patients who have developed multiple SCCs following renal transplantation should be considered for low-dose acitretin treatment (10 mg-30 mg/day) for secondary prevention.

Healthcare professionals should be aware that adverse effects are common, are dose related and may lead to dose reduction or discontinuation of treatment.

Follow Up

Patients with SCC with any high-risk features should be offered follow-up appointments every three to six months for 24 months following treatment. One further appointment at three years may be appropriate depending on the clinical risk.

Definitions

Levels of Evidence

1++: High quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias

1+: Well-conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias

1-: Meta-analyses, systematic reviews, or RCTs with a high risk of bias

2++: High quality systematic reviews of case control or cohort studies

High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal

2+: Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal

2-: Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal

3: Non-analytic studies (e.g. case reports, case series)

4: Expert opinion

Recommendations

Some recommendations can be made with more certainty than others. The wording used in the recommendations in this guideline denotes the certainty with which the recommendation is made (the 'strength' of the recommendation).

The 'strength' of a recommendation takes into account the quality (level) of the evidence. Although higher quality evidence is more likely to be associated with strong recommendations than lower quality evidence, a particular level of quality does not automatically lead to a particular strength of recommendation.

Other factors that are taken into account when forming recommendations include: relevance to the National Health Service (NHS) in Scotland; applicability of published evidence to the target population; consistency of the body of evidence, and the balance of benefits and harms of the options.

- For 'strong' recommendations on interventions that 'should' be used, the Guideline Development Group is confident that, for the vast majority of people, the intervention (or interventions) will do more good than harm.
- For 'conditional' recommendations on interventions that should be 'considered', the Guideline Development Group is confident that the

intervention will do more good than harm for most patients. The choice of intervention is therefore more likely to vary depending on a person's values and preferences, and so the healthcare professional should spend more time discussing the options with the patient.

## Clinical Algorithm(s)

An algorithm titled "SCC Management Algorithm" is provided in Annex 3 in the original guideline document.

# Scope

## Disease/Condition(s)

Squamous cell carcinoma (SCC)

Note: The guideline excludes: actinic keratoses, keratoacanthoma, squamous intra-epidermal carcinoma/carcinoma-in-situ (Bowen's disease), metastatic SCC, including in-transit metastasis, locoregional and distant metastasis, mucosal sites including internal mucosal lip, anogenital sites, SCC of the nail matrix bed, recurrent SCC, SCC arising in patients with cancer-predisposing genodermatoses such as xeroderma pigmentosum, recessive dystrophic epidermolysis bullosa, multiple self-healing squamous epithelioma of Ferguson Smith disease or albinism.

## Guideline Category

Management

Prevention

Risk Assessment

## Clinical Specialty

Dermatology

Oncology

Plastic Surgery

Radiation Oncology

Surgery

## Intended Users

Advanced Practice Nurses

Nurses

Patients

Physician Assistants

Physicians

## Guideline Objective(s)

- To help practitioners to more reliably identify the high-risk tumours which are most likely to metastasise
- To help to direct available resources to the management of patients with high-risk squamous cell carcinoma (SCC), thus reducing the incidence of metastatic SCC

- To help address the following concerns:
  - Treatment variability amongst practitioners currently managing SCC
  - That patients with high-risk SCC are not always referred to multidisciplinary team (MDT) meetings
  - The limitations of the current TNM classification in identifying those SCC most likely to metastasise
- To provide recommendations for referral, management and follow up of patients aged 18 years and over with primary invasive SCC

## Target Population

Patients aged 18 years and over with primary invasive squamous cell carcinoma (SCC)

## Interventions and Practices Considered

1. Consideration of high risk features:
   - Squamous cell carcinoma (SCC) arising in the ear
   - Tumour diameter >20 mm
   - Tumour depth >4 mm
   - Tumour extension beyond dermis into or through subcutaneous fat
   - Perineural invasion
   - Poorly differentiated
   - Desmoplastic subtype
   - Immunosuppression
2. Referral to skin cancer multidisciplinary team (MDT)
3. Standard surgical excision (with consideration of clinical peripheral margins)
4. Mohs micrographic surgery
5. Curettage and cautery
6. Photodynamic therapy (not recommended)
7. Primary and adjuvant radiotherapy
8. Low-dose acitretin treatment for secondary prevention
9. Follow-up (three to six months for 24 months)

## Major Outcomes Considered

- Local recurrence
- Nodal metastasis
- Disease-specific death

# Methodology

## Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

## Description of Methods Used to Collect/Select the Evidence

Systematic Literature Review

The evidence base for this guideline was synthesised in accordance with Scottish Intercollegiate Guidelines Network (SIGN) methodology. A systematic review of the literature was carried out using an explicit search strategy devised by a SIGN Evidence and Information Scientist. Databases searched include Medline, EMBASE, CINAHL, PsycINFO and the Cochrane Library. The year range covered was 2007-2012. Internet searches were carried out on various Web sites including the U.S. National Guideline Clearinghouse (NGC). The main searches were

supplemented by material identified by individual members of the development group. Each of the selected papers was evaluated by two members of the group using standard SIGN methodological checklists before conclusions were considered as evidence.

Please refer to the search narrative for further information on the search strategy, including search terms (see the "Availability of Companion Documents" field).

Literature Search for Patient Issues

At the start of the guideline development process, a SIGN Evidence and Information Scientist conducted a literature search for qualitative and quantitative studies that addressed patient issues of relevance to early management of patients with squamous cell carcinoma (SCC). Databases searched include Medline, EMBASE, CINAHL and PsycINFO, and the results were summarised by the SIGN Patient Involvement Officer and presented to the Guideline Development Group.

## Number of Source Documents

The literature search and screening processes retrieved 1729 abstracts when duplicates were removed. Of these 463 papers were identified and critically appraised.

## Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

## Rating Scheme for the Strength of the Evidence

Levels of Evidence

1++: High quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias

1+: Well-conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias

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3: Non-analytic studies (e.g. case reports, case series)

4: Expert opinion

## Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

## Description of the Methods Used to Analyze the Evidence

Once papers have been selected as potential sources of evidence, the methodology used in each study is assessed to ensure its validity. The result of this assessment will affect the level of evidence allocated to the paper, which will in turn influence the grade of recommendation that it supports.

The methodological assessment is based on a number of key questions that focus on those aspects of the study design that research has shown to have a significant influence on the validity of the results reported and conclusions drawn. These key questions differ between study types, and a range of checklists is used to bring a degree of consistency to the assessment process. Scottish Intercollegiate Guidelines Network (SIGN) has

based its assessments on the MERGE (Method for Evaluating Research and Guideline Evidence) checklists developed by the New South Wales Department of Health, which have been subjected to wide consultation and evaluation. These checklists were subjected to detailed evaluation and adaptation to meet SIGN's requirements for a balance between methodological rigour and practicality of use.

The assessment process inevitably involves a degree of subjective judgement. The extent to which a study meets a particular criterion—e.g., an acceptable level of loss to follow up—and, more importantly, the likely impact of this on the reported results from the study will depend on the clinical context. To minimise any potential bias resulting from this, each study must be evaluated independently by at least two group members. Any differences in assessment should then be discussed by the full group. Where differences cannot be resolved, an independent reviewer or an experienced member of SIGN Executive staff will arbitrate to reach an agreed quality assessment.

Evidence Tables

Evidence tables are compiled by SIGN executive staff based on the quality assessments of individual studies provided by Guideline Development Group members. The tables summarise all the validated studies identified from the systematic literature review relating to each key question. They are presented in a standard format to make it easier to compare results across studies, and will present separately the evidence for each outcome measure used in the published studies. These evidence tables form an essential part of the guideline development record and ensure that the basis of the Guideline Development Group's recommendations is transparent.

Additional details can be found in the companion document titled "SIGN 50: A Guideline Developers' Handbook." (Edinburgh [Scotland]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50]), available from the SIGN Web site .

## Methods Used to Formulate the Recommendations

Expert Consensus

## Description of Methods Used to Formulate the Recommendations

Synthesising the Evidence

Guideline recommendations are graded to differentiate between those based on strong evidence and those based on weak evidence. This judgement is made on the basis of an (objective) assessment of the design and quality of each study and a (perhaps more subjective) judgement on the consistency, clinical relevance and external validity of the whole body of evidence. The aim is to produce a recommendation that is evidence-based, but which is relevant to the way in which health care is delivered in Scotland and is therefore implementable.

It is important to emphasise that the grading does not relate to the importance of the recommendation, but to the strength of the supporting evidence and, in particular, to the predictive power of the study designs from which that data was obtained. Thus, the grading assigned to a recommendation indicates to users the likelihood that, if that recommendation is implemented, the predicted outcome will be achieved.

Considered Judgement

It is rare for the evidence to show clearly and unambiguously what course of action should be recommended for any given question. Consequently, it is not always clear to those who were not involved in the decision making process how guideline developers were able to arrive at their recommendations, given the evidence they had to base them on. In order to address this problem, Scottish Intercollegiate Guidelines Network (SIGN) has introduced the concept of considered judgement.

Under the heading of considered judgement, Guideline Development Groups summarise their view of the total body of evidence covered by each evidence table.

Each guideline group considers the following factors:

- Quantity, quality, and consistency of evidence
- External validity (generalisability) of studies
- Directness of application to the target population for the guideline
- Any evidence of potential harms associated with implementation of a recommendation
- Clinical impact (i.e., the extent of the impact on the target patient population, and the resources needed to treat them in accordance with the recommendation)
- Whether, and to what extent, any equality groups may be particularly advantaged or disadvantaged by the recommendations made

- Implementability (i.e., how practical it would be for the National Health Service (NHS) Scotland to implement the recommendation.)

Then the group is asked to summarise its view on all of these issues, both the quality of the evidence and its potential impact, before making a recommendation. This summary should be succinct, and taken together with its views of the level of evidence represent the first draft of the text that will appear in the guideline immediately before a recommendation.

Additional detail about SIGN's process for formulating guideline recommendations is provided in Section 7 of the companion document titled "SIGN 50: A Guideline Developers' Handbook." (Edinburgh [Scotland]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50], available from the SIGN Web site .

## Rating Scheme for the Strength of the Recommendations

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## Cost Analysis

A costing statement and a template have been published to support the implementation of the following two recommendations in National Health Service (NHS) Scotland:

1. Where high-risk features are present (see the "Major Recommendations" field for features), patients with primary squamous cell carcinoma (SCC) should be discussed at a skin cancer multidisciplinary team (MDT) meeting.
2. All SCC, including low-risk SCC, should be reported on a minimum dataset, which allows all high-risk SCCs to be fast-tracked to the MDT. Data on all SCC should be subject to clinical audit and sent to the Cancer Registry.

See the "Availability of Companion Documents" field for additional information.

## Method of Guideline Validation

External Peer Review

Internal Peer Review

## Description of Method of Guideline Validation

Specialist Review

This guideline was also reviewed in draft form by a group of independent expert referees, who were asked to comment primarily on the comprehensiveness and accuracy of interpretation of the evidence base supporting the recommendations in the guideline. The guideline group addresses every comment made by external reviewers, and must justify any disagreement with the reviewers' comments.

Scottish Intercollegiate Guidelines Network (SIGN) Editorial Group

As a final quality control check, the guideline is reviewed by an editorial group comprising the relevant specialty representatives on SIGN Council to ensure that the specialist reviewers' comments have been addressed adequately and that any risk of bias in the guideline development process as a whole has been minimized.

# Evidence Supporting the Recommendations

## Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

# Benefits/Harms of Implementing the Guideline Recommendations

## Potential Benefits

Appropriate management of patients with primary cutaneous squamous cell carcinoma (SCC)

## Potential Harms

- Acitretin-related side effects include headaches, rash, musculoskeletal symptoms and hyperlipidaemia.
- Previous guidelines recommend that radiotherapy should be used with caution on sites where the intervention is poorly tolerated such as the back of the hand, lower limb and where the tumour invades bone or cartilage.

# Contraindications

## Contraindications

- Radiotherapy is contraindicated in patients with previously irradiated sites and with genodermatoses predisposing to skin cancer.
- There are contraindications related to long term cosmesis in younger patients and the potential for radiation-induced second malignancy.

# Qualifying Statements

## Qualifying Statements

- This guideline is not intended to be construed or to serve as a standard of care. Standards of care are determined on the basis of all clinical data available for an individual case and are subject to change as scientific knowledge and technology advance and patterns of care evolve. Adherence to guideline recommendations will not ensure a successful outcome in every case, nor should they be construed as including all proper methods of care or excluding other acceptable methods of care aimed at the same results. The ultimate judgement must be made by the appropriate healthcare professional(s) responsible for clinical decisions regarding a particular clinical procedure or treatment plan. This judgement should only be arrived at following discussion of the options with the patient, covering the diagnostic and treatment choices available. It is, however, advised that significant departures from the national guideline or any local guidelines derived from it should be fully documented in the patient's case notes at the time the relevant decision is taken.
- Recommendations within this guideline are based on the best clinical evidence. Some recommendations may be for medicines prescribed outwith the marketing authorisation (MA) also known as product license. This is known as 'off label' use.
  Medicines may be prescribed outwith their product licence in the following circumstances:

- For an indication not specified within the marketing authorisation
- For administration via a different route
- For administration of a different dose
- For a different patient population

An unlicensed medicine is a medicine which does not have MA for medicinal use in humans.

Generally 'off label' prescribing of medicines becomes necessary if the clinical need cannot be met by licensed medicines within the marketing authorisation. Such use should be supported by appropriate evidence and experience.

"Prescribing medicines outside the conditions of their marketing authorisation alters (and probably increases) the prescribers' professional responsibility and potential liability."

The General Medical Council (GMC) recommends that when prescribing a medicine 'off label', doctors should:

- Be satisfied that such use would better serve the patient's needs than an authorised alternative (if one exists)
- Be satisfied that there is sufficient evidence/experience of using the medicines to show its safety and efficacy, seeking the necessary information from appropriate sources
- Record in the patient's clinical notes the medicine prescribed and, when not following common practice, the reasons for the choice
- Take responsibility for prescribing the medicine and for overseeing the patient's care, including monitoring the effects of the medicine

Non-medical prescribers should ensure that they are familiar with the legislative framework and their own professional prescribing standards.

Prior to any prescribing, the licensing status of a medication should be checked in the summary of product characteristics (SPC). The prescriber must be competent, operate within the professional code of ethics of their statutory bodies and the prescribing practices of their employers.

# Implementation of the Guideline

## Description of Implementation Strategy

Implementation of national clinical guidelines is the responsibility of each National Health Service (NHS) Board and is an essential part of clinical governance. Mechanisms should be in place to review care provided against the guideline recommendations. The reasons for any differences should be assessed and addressed where appropriate. Local arrangements should then be made to implement the national guideline in individual hospitals, units and practices.

Refer to Section 8 in the original guideline document for information on resource implications associated with implementing the key clinical recommendations and advice on audit as a tool to aid implementation.

## Implementation Tools

Audit Criteria/Indicators

Chart Documentation/Checklists/Forms

Clinical Algorithm

Mobile Device Resources

Patient Resources

Quick Reference Guides/Physician Guides

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

# Institute of Medicine (IOM) National Healthcare Quality Report Categories

## IOM Care Need

Getting Better

Living with Illness

## IOM Domain

Effectiveness

Patient-centeredness

# Identifying Information and Availability

## Bibliographic Source(s)

Scottish Intercollegiate Guidelines Network (SIGN). Management of primary cutaneous squamous cell carcinoma. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2014 Jun. 44 p. (SIGN publication; no. 140). [86 references]

## Adaptation

Not applicable: The guideline was not adapted from another source.

## Date Released

2014 Jun

## Guideline Developer(s)

Scottish Intercollegiate Guidelines Network - National Government Agency [Non-U.S.]

## Source(s) of Funding

Scottish Executive Health Department

## Guideline Committee

Guideline Development Group

## Composition of Group That Authored the Guideline

*Guideline Development Group*: Professor Charlotte Proby (*Chair*), Professor of Dermatology, Jacqui Wood Cancer Centre, Ninewells Hospital and Medical School, University of Dundee; Dr Andrew Affleck, Consultant Dermatologist and Dermatological Surgeon, Ninewells Hospital, Dundee; Dr Peter Bowden, Lay Representative, St Andrews; Ms Juliet Brown, Evidence and Information Scientist, SIGN; Ms Moira

Crumley, Clinical Nurse Specialist in Skin Cancer, Glasgow Royal Infirmary; Mr Roger Currie, Consultant Oral and Maxillofacial Surgeon, Crosshouse Hospital, Kilmarnock; Dr Alan Evans, Consultant Dermatopathologist, Ninewells Hospital, Dundee; Miss Katherine Farquhar, Medical Student, Glasgow; Ms Wilma Ford Macmillan, Skin Cancer Nurse Specialist, Western Infirmary, Glasgow; Dr Girish Gupta, Consultant Dermatologist, Monklands Hospital, Airdrie; Dr Khalid Hassan, General Practitioner/Associate Specialist in Dermatology, Vale of Leven Hospital, Alexandria; Dr Lorna Mackintosh, Consultant Dermatologist, Western Infirmary, Glasgow; Dr Marie Mathers, Consultant Histopathologist, Western General Hospital, Edinburgh; Dr Catriona McLean, Consultant Clinical Oncologist, Western General Hospital, Edinburgh; Dr Colin Moyes, Consultant Dermatopathologist, Southern General Hospital, Glasgow; Dr Lisa Naysmith, Consultant Dermatological Surgeon and Dermatologist, Royal Infirmary of Edinburgh; Dr Jonathan Norris, Consultant Dermatologist, Dumfries and Galloway Royal Infirmary, Dumfries; Ms Fiona Oakey, Skin Cancer Clinical Nurse Specialist, Glasgow Royal Infirmary; Mr Taimur Shoaib, Consultant Plastic Surgeon, Glasgow Royal Infirmary; Ms Leigh Smith, Lay Representative, Chair of Melanoma Action and Support Scotland; Ms Ailsa Stein, Programme Manager, SIGN; Dr Lorna Thompson, Programme Manager, SIGN

## Financial Disclosures/Conflicts of Interest

All members of the Guideline Development Group made declarations of interest. A register of interests is available in the supporting material section for this guideline at www.sign.ac.uk .

## Guideline Status

This is the current release of the guideline.

Any amendments to the guideline in the interim period will be noted on the Scottish Intercollegiate Guidelines Network (SIGN) Web site .

This guideline meets NGC's 2013 (revised) inclusion criteria.

## Guideline Availability

Electronic copies: Available from the Scottish Intercollegiate Guidelines Network (SIGN) Web site .

## Availability of Companion Documents

The following are available:

- Management of primary cutaneous squamous cell carcinoma: quick reference guide. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network; 2014 Jun. 10 p. Electronic copies: Available from the Scottish Intercollegiate Guidelines Network (SIGN) Web site .
- Management of primary cutaneous squamous cell carcinoma: costing statement. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network; 2015 Feb. 10 p. Electronic copies: Available from the SIGN Web site .
- Management of primary cutaneous squamous cell carcinoma: costing template. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network; 2015 Feb. 7 p. Electronic copies: Available from the SIGN Web site .
- Search narrative. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network. 2015 Feb. 3 p. Electronic copies: Available from the SIGN Web site .
- SIGN 50: A guideline developer's handbook. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network. (SIGN publication; no. 50). Electronic copies: Available from the SIGN Web site .

In addition, Section 10 in the original guideline document contains key points to audit. Annexes 2 and 5 of the original guideline document include examples of a histopathology request form and a pathology reporting pro forma.

Executive summaries of SIGN guidelines are available for mobile devices through the guidelines app on the SIGN Web site .

## Patient Resources

The following is available:

- Management of primary cutaneous squamous cell carcinoma. A booklet for patients and carers. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2014 Jul. 24 p. Electronic copies: Available from the Scottish Intercollegiate Guidelines Network (SIGN) Web site .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

## NGC Status

This NGC summary was completed by ECRI Institute on August 6, 2015. The information was verified by the guideline developer on September 30, 2015.

## Copyright Statement



# Disclaimer

## NGC Disclaimer